REMARKS

Claims 8 and 10-19 (as renumbered by the Examiner) were previously pending in this application. Claim 10 has been amended, claims 8 and 11-19 have been cancelled without prejudice to or disclaimer of the underlying subject matter, and new claims 20-25 have been added. Support for the new and amended claims can be found throughout the specification, for example, at page 40, lines 5-19, at page 16, lines 10-17, and at page 39, lines 11-19, in the sequence listing, and in the claims as originally filed. No new matter enters by way of these amendments or new claims.

I. Information Disclosure Statement

The Examiner indicated that she has attached "4 sheets" of an information disclosure statement. *See* Office Action at page 1. However, the Examiner attached page 1 of 3 and 2 copies of page 3 of 3 of the information disclosure statement, but no page 2 of 3. In addition, there was no page 4. Applicants respectfully request that the Examiner provide an initialed copy of page 2 of 3 of the information disclosure statement.

II. Election/Restrictions

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the finality of the requirement to elect a single nucleic acid sequence for exmaination, but maintaintheir traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the United States Patent and Trademark Office policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (MPEP, 8th ed., August 2001, Section 803.04). The MPEP

further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Based upon the foregoing, Applicants submit that the election requirement is improper and therefore must be withdrawn. To facilitate prosecution, however, Applicants have amended the claims to remove the non-elected sequences.

III. Claim Numbering

The Examiner has noted that a claim 10 was not previously pending and has thus renumbered previously added new claims 11-20 to 10-19. Applicants acknowledge the renumbering and will proceed using the claims as renumbered by the Examiner.

IV. Priority

The Examiner has noted that she has found support for SEQ ID NO: 7 in application number 09/955,974, and therefore considers the priority date of the instant application to be February 19, 1999. Applicants have amended the specification to reflect this priority data.

V. Claim Rejections – 35 U.S.C. § 101

Claims 10 and 17 have been rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility due to its not being supported by a substantial utility. Office Action page 4. Applicants respectfully disagree. Claim 17 has been cancelled without prejudice to or disclaimer of the underlying subject matter and claim 10 has been amended to comply with the Examiner's request to amend claims in light of the election, so Applicants will respond to the rejection only as it pertains to amended claim 10.

The Examiner contends that "the specification asserts different enzymes to the single elected sequence by database sequence alignments; first to copalyl diphosphate synthase enzyme and second to the accession number gi576885 - which is entered to be a kaurene synthase A." Office Action page 4. The Examiner thus concludes that "the elected sequence is asserted to be

at leasat [sic] two different enzymes with different functions of the gibberellin pathway [and that]...the specification discloses uncertainty as to which utility should be asserted to the instant nucleic acid." *Id.* Applicants respectfully disagree and draw the attention of the Examiner to page 3, lines 1-5 of the specification, which states that copalyl diphosphate synthase is also referred to as *ent*-kaurene synthetase A. Thus, what the Examiner refers to as two enzymes is actually two names for one enzyme. Further, the utility of the enzyme is described in the same section - the cyclization of geranlygeranyl diphosphate to copalyl diphosphate.

Next, the Examiner acknowledges that "applicant(s) have listed this sequence which is known in the prior art and which has a high percentage sequence similarity (95%, table A) to ... SEQ ID NO: 7," however, she contends that "even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases." Office Action at pages 4-5. However, the Examiner has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. A broad assertion of "unpredictability" in the art is not sufficient to reject the claimed invention for lack of utility.

The Examiner cites three publications published between 1994 and 1997 that allegedly "support this unpredictability." Office Action page 5. In response, Applicants refer the Examiner to the following articles (see Information Disclosure Statement submitted herewith) where sequence similarity is routinely used by those of ordinary skill in the art as a valuable predictor of function. *See, e.g.,* Venter *et al.*, The Sequence of the Human Genome, *Science*, 291: 1304-1351 (2001); Woese *et al.*, Conservation of Primary Structure in 16S rRNA, *Nature*, 254: 83-85 (1975).

Finally, even it the Examiner maintains her position on the above utilities, the specification describes multiple other utilities for the present invention, including isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, cis-regulatory elements; identifying polymorphisms, and as probes for assisting in the isolation of full-length cDNAs or genes, gene mapping, isolation of homologous sequences, and detection of gene expression. *See, e.g.*, specification at page 57, line 3 *et seq*, under the heading "Uses of the Agents of the Invention."

It is well established that "when a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. Moreover, the utilities described above and disclosed throughout the present specification are applicable, for example, in identifying elements related to the gibberellin pathway and to copalyl diphosphate synthase.

Many of these uses are directly analogous to a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that they do "not define a 'real world' content or use." Office Action page 6. The Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs.

Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Claim Rejections – 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner has rejected claims 10 and 17 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action page 6. Applicants respectfully disagree. Claim 17 has been cancelled without prejudice to or disclaimer of the underlying subject matter and claim 10 has been amended to comply with the Examiner's request to amend claims in light of the election, thus Applicants will respond to the rejection only as it pertains to amended claim 10.

Applicants assert that the rejection is erroneous and has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VII. Claim Rejections – 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has rejected claims 10 and 17 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at page 7. Applicants respectfully disagree. Claim 17 has been cancelled without prejudice to or disclaimer of the underlying subject matter and claim 10 has been amended to comply with the Examiner's request

to amend claims in light of the election, thus Applicants will respond to the rejection only as it pertains to amended claim 10.

Although the Examiner acknowledges that the specification discloses SEQ ID NO: 7, claim 10 allegedly fails to meet the written description requirement because "the specification does not teach the large genus that is encompassed by the claim." Office Action page 7. Applicants respectfully disagree with this contention.

An adequate written description of a genus of nucleic acids, as recited in claim 10 may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession

of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that "the claims are directed to encompass gene sequences of any magnitude and/or content comprising SEQ ID NO: 7...Therefore, the specification does not teach the large genus that is encompassed by the claim." Office Action pages 6-7. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. Applicants respectfully disagree. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-1569, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 7. Moreover, nucleic acid molecules falling within the scope of claim 10 are readily identifiable – they comprise a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 7. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claim 10.

The Examiner further contends again that the "specification is uncertain and inconsistent with that which is representative [of] SEQ ID NO: 7." Office Action page 7. Applicants respectfully disagree. As Applicants pointed out in the response to the utility rejection above, page 3, lines 1-5 of the specification states that copalyl diphosphate synthase **is also referred to as** *ent*-kaurene synthetase A.

Therefore, claim 10 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

VIII. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 10 and 17 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action page 7. The Examiner contends that claim 10 is "vague and indefinite due to the lack of clarity of the phrase 'comprises a nucleic acid sequence of SEQ ID NO: 7' as seen in claim 17, line 2." Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991).

Applicants respectfully assert that the meaning of the phrase "comprising a nucleic acid sequence of SEQ ID NO: 7" is readily understandable by one of skill in the art. Moreover, the use of the transitional phrase "comprising" is well-understood to patent practitioners. *See, e.g.*, MPEP § 2111.03. The rejection of claim 10 under 35 U.S.C. § 112, second paragraph, is thus improper. Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claims 4 and 5 under 35 U.S.C. § 112, second paragraph.

IX. Claim Rejections – 35 U.S.C. § 102

Claims 10 and 17 have been rejected under 35 U.S.C. § 102, as allegedly being anticipated by GenBank Accession Number L37750 (gi 576885; 03-Aug-1995). Office Action page 8. Applicants respectfully disagree. The Examiner bases this rejection on the assertion that "the instant sequence of accession number L37750 anticipates the requirements of the claims wherein the 'nucleic acid sequence comprises a nucleic acid sequence of SEQ ID NO: 7.' " Office Action at page 8. In response, Applicants respectfully reiterate their arguments with respect to the rejection under 35 U.S.C. § 112, second paragraph, herein.

Moreover, "[i]t is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Further, "an anticipation rejection

requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q 619, 621 (Fed. Cir. 1985). The Examiner has applied an untenable interpretation of claim 10 to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, around 150 contiguous nucleotides, and thus concludes that the claim is anticipated by the cited reference. Office Action at page 8. Pending claim 10 is directed to a nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 7 or its complement. Whatever else Genbank teaches, it does not disclose SEQ ID NO: 7. Absent a teaching of each and every element of the claim, including the nucleotide sequence of SEQ ID NO: 7, the reference cited by the Examiner does not anticipate claim 10.

In view of the above, Applicants contend that the rejection under 35 U.S.C. § 102(b) over Genbank is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 10 and 17 have also been rejected under 35 U.S.C. § 102, as allegedly being anticipated by products O1256 and O4378 of the 1993 Sigma Chemical Catalogue. The Examiner alleges that product O1256 in the 1993 Sigma Chemical Catalog, which is a 4-mer oligonucleotide of poly dT nucleotides, and product O4378, which is a 4-mer oligonucleotide of poly dA nucleotides, anticipate claim 10. Applicants respectfully disagree.

As stated above,"[i]t is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech,* 802 F.2d at 1369. Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d at 534. The Examiner has applied an untenable interpretation of claim 10 to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, molecules as short as four codons, and thus concludes that the claim is anticipated by the cited reference. Office Action at page 8. Pending claim 10 is directed to a nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 7 or its complement. Whatever else the 1993 Sigma Catalogue teaches, it does not disclose SEQ ID NO: 7. Absent a teaching of each and every element of the claim, including the nucleotide sequence of SEQ ID NO: 7, the reference cited by the Examiner does not anticipate claim 10.

In view of the above, Applicants contend that the rejection under 35 U.S.C. § 102(b) over Genbank is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

In view of the above, Applicants contend that the rejection under 35 U.S.C. § 102(b) over Sigma is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

X. Claim Objection

Claim 17 has been objected to under 37 C.F.R. 1.75(c) for allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have cancelled claim 17 without prejudice to or disclaimer of the underlying subject matter. Therefore, the claim objection is rendered moot and withdrawal of this objection is respectfully requested.

XI. Specification Objection

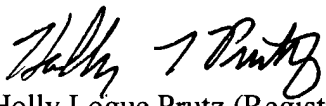
The specification has been objected to because it allegedly contains embedded hyperlinks and/or other forms of browser executable code. Office Action page 8. According to M.P.E.P. §608.01, embedded hyperlinks and browser executable code are not permitted. Applicants draw the attention of the Examiner to the Preliminary Amendment filed September 19, 2001, where Applicants amended the specification to remove the phrase "http://." Applicants request that the objection to the specification be withdrawn in light of the previously filed preliminary amendment.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested.

The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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